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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,772	04/21/2005	Philip Bickford Smith	15975US	6668

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EXAMINER	
ANDERSON, MICHAEL J	
ART UNIT	**PAPER NUMBER**
3767	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,772	BICKFORD SMITH ET AL.	
	Examiner	Art Unit	
	Michael J. Anderson	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *21 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/21/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The abstract of the disclosure is objected to because it exceeds the limit of <150 words. Correction is required. See MPEP § 608.01(b).

Information Disclosure Statement

1. An initialed and dated copy of Applicant's IDS form 1449 filed 4/21/2005, is attached to the instant Office action.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Segal (US patent # 6,402,207) (Segal).

4. With regard to claim 1 Segal discloses, a system of medical small bore tubing for multiple different applications (figures 1-7), the system in each application comprising connectors (element # 1) between tubing (36, 505) of the system or components of the system (figures 1-7), wherein said connectors comprise: a male component (1) having a stub (15), a first key (29) and a through-bore (4) for the passage of fluid to be

transported; and a female (3) component having a stub (30), a second key (35) and a through-bore (4) for the passage of fluid to be transported; said male and female components being adapted to be interconnected in a fluid-tight manner with inter-engagement of said first and second keys, and said stubs being adapted for connection to tubing of the system or components of the system (figure 2), and at least one of said male and female components having a grip (32); wherein, in each application: a) the first and second keys are unique to each application of the system so that they prevent connection of a female component of one application to a male component of another application (figures 2-7); and b) said grip has application affordance unique to the application for which it is intended (figure 5), the affordance comprising both visual and tactile cues (figure 5),; wherein misconnections between tubing and components of said different applications of the system are prevented and attempts by users to effect said misconnection are discouraged by said affordance of said grip (figures 5 and 7).

5. With regard to claim 2, Segal discloses as for claim 1 and further discloses, wherein said application affordance comprises a shape of the grip that is suggestive of a part of a human body for which the application is intended (column 8, lines 33-49).

6. With regard to claim 3, Segal discloses as for claim 2 and further discloses, wherein a first application is neuraxial, and said shape of the grip is generally cylindrical having a longitudinal spine and encircling ribs suggestive of the human spine and ribs (figure 7A, and column 8, lines 33-49).

7. With regard to claim 4, Segal discloses as for claim 2 and further discloses, wherein a second application is respiratory, and said shape of the grip is generally cylindrical having alternating frusto-conical sections suggestive of a bellows (figures 5 and 7; column 6, lines 37-64, and column 8, lines 33-49).

8. With regard to claim 5, Segal discloses as for claim 2 and further discloses, wherein a third application is enteral, and said shape of the grip is generally cylindrical with bulges down its length suggestive of the human colon (figures 5 and 7; column 6, lines 37-64, and column 8, lines 33-49).

9. With regard to claim 6, Segal discloses as for claim 2 and further discloses, wherein said visual and tactile cues of the application affordance are provided only by said shape of the grip (figures 5 and 7; column 6, lines 37-64, and column 8, lines 33-49).

10. With regard to claim 7, Segal discloses as for claim 1 and further discloses wherein said grip also comprises a mechanism affordance unique to a method of interconnection between said male and female components (figures 2, 3, 5 and 7; column 6, lines 37-64, and column 8, lines 33-49).

11. With regard to claim 8, Segal discloses as for claim 7 and further discloses, wherein said method of interconnection comprises a twisting step (figure 1 locking

system must be twisted); and wherein said mechanism affordance comprises a wing of said grip (figure 2, elements 29 and 35).

12. With regard to claim 9, Segal discloses as for claim 7 and further discloses, wherein said method of interconnection comprises a pushing step (figure 1 locking system must be pushed); and wherein said mechanism affordance comprises a waist of said grip (figure 2, elements 29 and 35).

13. With regard to claim 10, Segal discloses as for claim 7 and further discloses, wherein said method of interconnection comprises a locking step (figure 1 locking system); and wherein said mechanism affordance comprises a button of said grip (figure 2, elements 29 and 35 and figure 6)..

14. With regard to claim 11, Segal discloses as for claim 1 and further discloses the kit comprising: a first converter having: a through bore; a standard female connector; a different male connector element; and a latching mechanism on the different male connector adapted to engage a flange of a corresponding female connector to which said different male connector is sealingly mateable (figures 4 and 6); and a second converter having: a through bore; a standard male connectors; a different female connector that corresponds with the different male connector of said first converter (figures 4 and 6); and a flange adapted for engagement with the latching mechanism of said first converter (figures 4 and 6).

15. With regard to claim 12, Segal discloses as for claim 11 and further discloses in which said standard connectors are 6% luer connectors (figure 2, elements 50 and 55).

16. With regard to claim 13, Segal discloses as for claim 11 and further discloses in which said different connectors are reduced-diameter 6% conical connectors (figure 4).

17. With regard to claim 14, Segal discloses as for claim 13 and further discloses in which said reduced-diameter comprises about 3 mm for the end of the male connector, and about 3.3 mm for the opening of the female connector, and wherein each connector has a length of about 7.5 mm (figure 4).

18. With regard to claim 15, Segal discloses as for claim 11 and further discloses a syringe (figure 7, 545), the syringe having a standard outlet (figure 7); wherein the standard outlet is permanently secured to the first converter (figure 7).

19. With regard to claim 16, Segal discloses as for claim 15 and further discloses wherein the standard outlet is permanently secured to the first converter by welding or adhering said first converter to said outlet (columns 7-8).

20. With regard to claim 18, Segal discloses as for claim 11 and further discloses a hypodermic needle (545), said needle having said different female connector formed directly thereon (figures 4 and 7 column 8, lines 50-67).

21. With regard to claim 19, Segal discloses as for claim 11 and further discloses, wherein said latching mechanism comprises a threaded collar and said flange comprises thread elements (column 9, lines 17-65).

22. With regard to claim 20, Segal discloses as for claim 19 and further discloses wherein the latching mechanism on the first converter is axially slidable between limits, and is rotatably free (figures 2, 4 and 6).

23. With regard to claim 21, Segal discloses as for claim 11 and further discloses, wherein the latching mechanism is visually coded to identify a class of medical applications for which it is intended (figures 5 and 7; column 6, lines 1-64, and column 8, lines 33-49).

24. With regard to claim 22, Segal discloses as for claim 11 and further discloses, wherein the standard male connector of said second converter has an integral latching mechanism formed thereon adapted to co-operate with flange elements provided on the standard female connector of said first converter to lock said standard male and female connectors together (figures 2, 4 and 6).

25. With regard to claim 23, Segal discloses as for claim 11 and further discloses, wherein said different female connector comprises a face having castellations; and

wherein leak paths are provided between said castellations in the event that a standard male connector is butted against said face (columns 6-8).

26. With regard to claim 24, Segal discloses as for claim 11 and further discloses, the syringe comprising an outlet having a different male connector to a standard male connector and a latching mechanism on the different male connector adapted to engage a flange of a corresponding female connector to which said different male connector is sealingly mateable (figures 4 and 6) .

27. With regard to claim 25, Segal discloses as for claim 11 and further discloses, component of medical tubing having a standard male connector and a standard female connector to which a first connector and a second connector of a kit as claimed in claim 11 have been connected (figures 1-7).

28. With regard to claim 26, Segal discloses as for claim 25 and further discloses, wherein the standard female connector of said first converter comprises flange elements; and wherein the standard male connector of said second converter has an integral latching mechanism formed thereon adapted to co-operate with the flange elements on of the standard female connector of said first converter to lock said standard male and female connectors together, and wherein said connections have been rendered permanent by application of adhesive between a latching mechanism on the component and the standard female connector of the first converter and between

the latching mechanism of the second converter and the female connector of the component (columns 7-8).

29. With regard to claim 27, Segal discloses as for claim 25 and further discloses, which component is a filter, valve or tube junction (figure 7).

30. With regard to claim 31, Segal discloses as for claim 1 and further discloses, the article comprising: a connector having a male or female component, a stub, a grip, a key and a through-bore for the passage of fluid to be transported, said component being adapted to be connected in a fluid-tight manner with a corresponding component of another connector and with inter-engagement of said key with the key of said other component, and said stub being connected to said article; wherein said grip has application affordance unique to the application for which the article is intended, the affordance comprising both visual and tactile cues.

Claim Rejections - 35 USC § 103

31. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 17, 28-30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Segal in view of Moberg (US patent # 6,659,980) (Moberg). Segal teaches as for claims 11 and 16. Segal does not teach permanent ultrasonic welding or adhesion. Moberg teaches ultrasonic welding and adhesion.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify Segal as taught by Moberg for the purpose of creating a permanent connection. One skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success.

Conclusion

References considered pertinent to Applicants' disclosure are listed on form PTO-892. All references listed on form PTO-892 are cited in their entirety.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Anderson whose telephone number is (571) 272-2764. The examiner can normally be reached on M-F 7:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael J Anderson
Examiner
Art Unit 3767

MJA
2/28/2007

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER